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SEP 28 2006  
PATENT & TRADEMARK OFFICE

Total Number of Pages in This Submission 8

Application Number 10/582,461

Filing Date 6/12/2006

First Named Inventor Look

Art Unit Unassigned

Examiner Name Unassigned

Attorney Docket Number AM-101358

## ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
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<input type="checkbox"/> Reply to Missing Parts/ Incomplete Application	<input type="checkbox"/> Landscape Table on CD	
<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53		
<p><b>Remarks</b>            Express Mail Number: EO 925 269 098 US            Customer Number: 38199</p>		

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	HOWSON AND HOWSON		
Signature			
Printed name	Mary E. Bak		
Date	Sept 28, 2006	Reg. No.	31,215

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No. : 10/582,461 Confirmation No.:

Applicant : Look et al.

Filed : June 12, 2006

TC/A.U. : unassigned

Examiner : unassigned

Customer No. : 38199

Title : METHODS FOR PRODUCING STORAGE STABLE VIRUSES  
AND IMMUNOGENIC COMPOSITIONS THEREOF

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Sir:

Applicant submits to the Examiner the attached Form PTO/SB/08A/B document listing and this paper pursuant to 37 CFR § 1.56 and § 1.97-1.98. Form PTO/SB/08A/B is attached and copies of the documents are enclosed herewith. This Information Disclosure Statement is submitted more than three months from the filing date of this application, but before the receipt of a first Office Action. Therefore, no fees are believed due.

The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper or during the pendency of this application, or credit any overpayment in any fees to our Deposit Account No. 08-3040.

Express Mail No. EO 925 269 098 US

**REMARKS**

Listed below are documents cited in the International Search Report dated September 9, 2005 in the corresponding International Patent Application No. PCT/US2004/041803, filed December 10, 2004. A copy of the Report is enclosed, together with copies of the documents.

- (i) International Patent Publication No. WO 03/086443, published October 23, 2003
- (ii) US Patent No. 4,273,762, issued June 16, 1981
- (iii) MAKOSCHEY et al., "Serum-Free Produced Bovine Herpesvirus Type 1 and Bovine Parainfluenza Type 3 Virus Vaccines are Efficacious and Safe", *Cytotechnol.*, 39(3):139-145 (2002)
- (iv) TANNOCK et al., "Freeze-Drying of Respiratory Syncytial Viruses for Transportation and Storage", *J. Clin. Microbiol.*, 25(9):1769-1771 (1987)
- (v) PHILLIPS et al., "A Study of Water Binding in Lyophilized Viral Vaccine Systems", *Cryobiology*, 18(4):414-419 (August, 1981)
- (vi) International Patent Publication No. WO 02/09749, published February 7, 2002
- (vii) International Patent Publication No. WO 04/017990, published March 4, 2004
- (viii) LABCONCO, "FreeZone 1 Liter Benchtop Freeze Dry Systems: User's Manual" [Online] from [www.labconco.com/manual/freeze](http://www.labconco.com/manual/freeze), page 24, 2003
- (ix) International Patent Publication No. WO-99/62500, published December 9, 1999
- (x) JACKSON et al., "Safety of a Trivalent Live Attenuated Intranasal Influenza Vaccine, FluMist™, Administered in Addition to Parenteral Trivalent Inactivated Influenza Vaccine to Seniors with Chronic Medical Conditions", *Vaccine*, 17(15-16):1905-1909 (April 9, 1999)
- (xi) International Patent Publication No. WO 02/28422, published April 11, 2002

The month of publication for documents AR, AS, AV, AAR, AAU, AAW-AAY, and BW-BY could not be determined. The years of publication for documents AR, AV, AAR, AAU, AAX, and BW-BY are sufficiently earlier than the effective US filing date and/or the foreign priority date of the present application so that the particular month of publication of the documents is not in issue (MPEP 609).

The Examiner is respectfully requested to consider the enclosed document identified in this paper and in the attached Form PTO/SB/08A/B during the course of examination of this application.

Respectfully submitted,

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Attorneys for Applicants

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STATEMENT BY APPLICANT**  
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Sheet

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of

4

**Complete if Known**

Application Number	10/582,461
Filing Date	June 12, 2006
First Named Inventor	Look et al.
Art Unit	unassigned
Examiner Name	unassigned

Attorney Docket Number

AM-101358

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
AA	US-4,084,330	04-18-1978	FRASER		
AB	US-5,489,266	02-06-1996	GRIMARD		
AC	US-5,732,837	03-31-1998	JONES		
AD	US-5,882,651	03-16-1999	MURPHY et al.		
AE	US-5,932,222	08-03-1999	RANDOLPH et al.		
AF	US-6,077,514	06-20-2000	MAASAB et al.		
AG	US-6,284,254	09-04-2001	MURPHY et al.		
AH	US-6,410,023	06-24-2002	DURBIN et al.		
AI	US-5,993,824	11-30-1999	MURPHY et al.		
AJ	US-4,273,762	06-16-1981	MCALEER et al.		

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>4</sup>
		Country Code <sup>2</sup> - Number <sup>3</sup> -Kind Code <sup>3</sup> (if known)				
AL	WO-03/086443		10-23-2003	TRUONG-LE		
AM	WO-02/09749		03-04-2004	PARRINGTON		
AN	WO-04/017990		03-04-2004	DOMINOWSKI		
AO	WO-99/62500		12-09-1999	VOLKIN et al.		
AP	WO-02/28422		04-11-2002	COLAU et al.		

Examiner Signature		Date Considered
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Sheet 2 of 4

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Application Number	10/582,461
Filing Date	June 12, 2006
First Named Inventor	Look et al.
Art Unit	unassigned
Examiner Name	unassigned

Attorney Docket Number

AM-101358

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
AR	ARYA	"Stabilization of Vaccines: To Be or Not To Be", Vaccine, 19:595-597 (2001)	
AS	CARPENTER et al.	"5 - Rational Design of Stable Lyophilized Protein Formulations: Theory and Practice", in <i>Rational Design of Stable Protein Formulations</i> , Kluwer Academic/Plenum Publishers, New York, NY: 109-33 (2002)	
AT	CHANOCK et al.	"Serious Respiratory Tract Disease Caused by Respiratory Syncytial Virus: Prospects for Improved Therapy and Effective Immunization" Pediatrics, 90:137-142 (July 1, 1992)	
AU	CROWE et al.	"Current Approaches to the Development of Vaccines Against Disease Caused by Respiratory Syncytial Virus (RSV) and Parainfluenza Virus (PIV): A Meeting Report from the WHO Programme for Vaccine Development" Vaccine, 13:415-421 (March, 1995)	
AV	FRANKS et al.	"Freeze-Drying: from Empiricism to Predictability. The Significance of Glass Transitions" Dev. Biol. Stand., 74:9-18 (1992)	
AW	GLEZEN et al.	"Risk of Respiratory Syncytial Virus Infection for Infants from Low-Income Families in Relationship to Age, Sex, Ethnic Group, and Maternal Antibody Level", J. Pediatr. 98:708-715 (May, 1981)	
AX	GUPTA et al.	"Restoration of Suppressor T-Cell Functions in Children with AIDS Following Intravenous Gamma Globulin Treatment", Am. J. Dis. Child., 140:143-146 (February, 1986)	
AY	GUPTA et al.	"Stabilization of RSV Against Thermal Inactivation and Freeze-Thaw Cycles for the Development and Control of RSV Vaccines and Immune Globulin" Vaccine, 14:1417-1420 (October, 1996)	
AZ	HAMBLING et al.	"Survival of the RSV During Storage Under Various Conditions, Br. J. Exp. Pathol., 45:647-655 (December, 1964)	
AAR	HATLEY	"The Effective Use of Differential Scanning Calorimetry in the Optimisation of Freeze-Drying Processes and Formulations", Dev. Biol. Stand. 74:105-119 (1992)	
AAS	HILLEMAN et al.	"Improving the Heat Stability of Vaccines: Problems, Needs, and Approaches", Rev. Infect. Dis., 11(Suppl. 3): S613-616 (May-June, 1989)	
AAT	JACKSON et al.	"Safety of a Trivalent Live Attenuated Intranasal Influenza Vaccine, FluMist™, Administered in Addition to Parenteral Trivalent Inactivated Influenza Vaccine to Seniors with Chronic Medical Conditions", Vaccine, 17(15-16):1905-1909 (April 9, 1999)	

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>			Application Number	10/582,461
			Filing Date	June 12, 2006
			First Named Inventor	Look et al.
			Art Unit	unassigned
			Examiner Name	unassigned
Sheet	3	of	4	Attorney Docket Number
NON PATENT LITERATURE DOCUMENTS				

Examiner Initials*	Cite No. <sup>1</sup>	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
AAU	KATZ et al., "Appendix N: Prospects for Immunizing Against Respiratory Syncytial Virus", in <i>New Vaccine Development Establishing Priorities</i> , Vol. 1, Washington, National Academic Press, pp. 397-409 (1985)		
AAV	KNEYBER et al., "Current Concepts on Active Immunization Against Respiratory Syncytial Virus for Infants and Young Children" <i>Pediatr. Infect. Dis. J.</i> , 21(7):685-696 (July, 2002)		
AAW	LABCONCO, "FreeZone 1 Liter Benchtop Freeze Dry Systems: User's Manual" [Online] from <a href="http://www.labconco.com/manual/freeze">www.labconco.com/manual/freeze</a> , page 24 (2003)		
AAX	LEMON et al., "The Thermostability of Vaccines", <i>Int. J. Technol. Assess. Health Care</i> , 10(1):177-184 (1994)		
AAY	MAKOSCHEY et al., "Serum-Free Produced Bovine Herpesvirus Type 1 and Bovine Parainfluenza Type 3 Virus Vaccines are Efficacious and Safe", <i>Cytotechnol.</i> , 39(3):139-145 (2002)		
AAZ	MARTIN et al., "Epidemiology of Respiratory Viral Infection Among Paediatric Inpatients Over a Six-year Period in North-East England", <i>J. Lancet</i> , 1035-1038 (November 11, 1978)		
BR	MCCONNOCHIE et al., "Variation in Severity of Respiratory Syncytial Virus Infections with Subtype", <i>J. Pediatr.</i> , 117(1):52-62 (July, 1990)		
BS	MELNICK et al., "Effect of pH on Thermal Stabilization of Oral Poliovirus Vaccine by Magnesium Chloride", <i>Proc. Soc. Exp. Biol. Med.</i> , 112:894-897 (April, 1963)		
BT	PHILLIPS et al., "A Study of Water Binding in Lyophilized Viral Vaccine Systems", <i>Cryobiology</i> , 18(4):414-419 (August, 1981)		
BU	RASMUSSEN et al., "Inadequate Poliovirus Immunity Levels in Immunized Illinois Children", <i>Am. J. Dis. Child.</i> , 126:465-469 (October, 1973)		
BV	ROBBINS et al., "Obstacles to Developing Vaccines for the Third World" <i>Sc. Am.</i> , 259:126-133 (November, 1988)		
BW	STARK et al., "Occurrence of Respiratory Syncytial Virus Subtypes in Hospitalized Children in Cleveland, Ohio from 1985-1988", <i>Pediatr. Pulmonol.</i> , 11:98-102 (1991)		

Examiner Signature	Date Considered
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## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

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Sheet 4 of

Sheet 4 of 4 Attorney Docket Number AM-101358

## NON PATENT LITERATURE DOCUMENTS

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